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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/599,692	10/05/2006	Prediman K. Shah	67789-101US0	2885

50670 7590 04/04/2012

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EXAMINER	
EPPS -SMITH, JANET L	

ART UNIT	PAPER NUMBER
1633	

NOTIFICATION DATE	DELIVERY MODE
04/04/2012	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/599,692	SHAH ET AL.	
	Examiner	Art Unit	
	Janet Epps-Smith	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 July 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5-27-11; 5-27-11; 5-27-11; 7-1-11; 9-1-11; 2-27-11*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-16 and 29-35 were cancelled by Applicants.

2. Claims 17-28 are now pending for examination.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Continued Examination Under 37 CFR 1.114

4. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 07/06/2010 has been entered.

Response to Arguments

Claim Rejections - 35 USC § 103

5. The rejection of Claims 17-28 under 35 U.S.C. 103(a) as being obvious over Fan et al. in view of Oka et al. and Sharif et al. is withdrawn in response to Applicant's submission of Declarations under 37 CFR 1.131 from the inventors of the instant invention. The Declarations of Drs. Shah, Chatterjee, and Wong are sufficient to overcome the Oka et al. reference.

6. Claims 17-28 remain rejected under 35 U.S.C. 103(a) as being obvious over Fan et al., Sharif et al., and Rader et al. (WO2004/108922A2) in view of Samulski et al. (US20020136710A1).

Fan et al. teach the AAV-based delivery of human apolipoprotein A-I into the skeletal muscle for the treatment of atherosclerosis. Page 1435 of this reference describes the construction of the AAV-based plasmid vectors, the vectors where designed to comprise the 5' and 3' ITRs of AAV-2, see the following schematic representation of the vectors used in this reference:

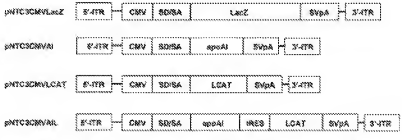

Figure 1 Schematic representation of AAV-based plasmid expression vectors. The various expression cassettes are flanked and were synthesized as described in the Materials and methods section. ITR, inverted terminal repeat of AAV; CMV, cytomegalovirus IE promoter/enhancer; SD/SA, SV40 intron; pA, SV40 virus polyadenylation site/signal; LacZ, E. coli β-galactosidase coding region; apoAI, human apoAI cDNA; LCAT, human LCAT cDNA. The plasmid backbone is not included and the diagrams are not to scale.

Sharif et al. teach adeno-associated virus mediated Apo A-I Milano gene therapy for the treatment of atherosclerosis and restenosis. Sharif et al. provided preliminary data using in vivo studies demonstrating successful gene transcription in vivo. In order to increase production of Apo A-I Milano, the AAV vector was optimized.

[Although, Applicants argued at pages 4-5 of their arguments filed 07/06/2010 that the Sharif et al. reference does not describe what effect the expression of recombinant apo-a-1 milano would have on atherosclerosis, there is clear suggestion and motivation in the prior art for the ordinary skilled artisan to design a method for

treating atherosclerosis comprising the administration of recombinant apolipoprotein-A-1 milano for the treatment of this disease. Applicant's arguments do not take the place of evidence of lack of enablement of the disclosure of Sharif et al.*]*

Rader et al. (WO2004/108922A2) teach a method for treating heart disease comprising the administration of a viral vector carrying an apolipoprotein A gene, see the following at page 34 of this reference:

> 17. A method of treating atherosclerosis in a subject, said method comprising the step of delivering to the subject a recombinant adeno-associated virus (rAAV) comprising an capsid protein selected from serotype 7 or 8, said rAAV comprising a gene encoding a human apolipoprotein (apoE) or human apolipoprotein A under the control of a regulatory control sequences which direct expression of the gene, said regulatory control sequences comprising a liver-specific promoter.

However, the above references do not teach wherein the administration comprises delivery to bone marrow cells.

Samulski et al. teach a method to facilitate or enhance delivery of a nucleic acid *in vivo* comprising the use of AAV vectors, the method comprising AAV infection into bone marrow progenitor cells. See the following: at ¶ [0099]: "[T]he present invention is also advantageously employed to facilitate or enhance delivery of a nucleic acid to a cell in vitro or in vivo, e.g., for gene therapy. In particular, the invention can be used to deliver or transfer nucleic acids to animal cells. According to this aspect of the invention, a cell is contacted with a receptor-like molecule that mediates AAV attachment and infection (as defined above) and with a rAAV vector carrying a nucleic acid to be delivered or transferred to the cell. The cell may be one that is normally non-

permissive or permissive for AAV infection. Generally, however, this embodiment of the invention is practiced with cells that normally exhibit no, or a low level, of ***AAV infection (e.g., bone marrow progenitor cells, airway epithelial cells, megakaryocytes).***"

Absent evidence of unexpected results, it would have been obvious to the ordinary skilled artisan to modify the teachings of Fan et al., Sharif et al., Rader et al. and Samulski et al. in the design of the claimed invention.

One of ordinary skill in the art would have been motivated to combine the teachings of Fan et al., Sharif et al. and Rader et al. in the design of a method for treating heart disease comprising the administration of an apolipoprotein A-1 gene in an AAV delivery vector since all of these references teach various forms of this method. In regards to treatment via delivery to bone marrow cells, absent evidence to the contrary, Samulski et al. provide sufficient guidance and suggestion for the skilled artisan to enhance delivery of AAV vectors *in vivo* for gene therapy purposes comprising delivery via bone marrow AAV infection.

In regards to the various limitations recited in claim 23 regarding the amount of vector administered to a mammal, since the general conditions of the claimed invention are disclosed in the prior art, absent evidence to the contrary, as per MPEP § 2144.05 [R-5], "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Moreover, regarding the rationale for combining prior art elements according to known methods to yield predictable results, all of the claimed elements were known in

the prior art and one skilled in the art could have combined the element as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet Epps-Smith whose telephone number is (571)272-0757. The examiner can normally be reached on M-F, 10AM-6:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571)-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Janet L. Epps-Smith/
Primary Examiner, Art Unit 1633